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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,054	09/24/2003	Jing Yang	CEN 5015USNP	7792
27777	7590	08/16/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HUFF, SHEELA JITENDRA	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/671,054	YANG ET AL.
	Examiner Sheela J. Huff	Art Unit 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 June 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) 11-16 and 18 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-10 and 17 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 24 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 11/1/04; 1/22/04.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: Notice to comply and EXHIBIT A.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-10 and 17 in the reply filed on 6/21/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16 and 18 are withdrawn from consideration as being drawn to an un-elected invention.

Information Disclosure Statement

The IDS filed 11/1/04 has been considered and an initialed copy of the PTO-1449 is enclosed.

The information disclosure statement filed 1/22/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. All of the reference have been considered except for the Brizzard et al reference. An initialed PTO-1449 is enclosed.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or

Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Specifically, page 9 of the specification contains sequences that are not part of the filed CRF.

Drawings

The drawings are objected to because the Brief Description of Figure 2 refers to A and B. However in figure A and B are not present.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 3-4 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. In claim 3 "tage" should be --tag--.
- b. Claim 17 depends from a non-elected invention.
- c. Claim 4 is unclear because it claims a polypeptide of claim comprising SEQ ID NO. 1, but SEQ ID No. contains a Flag peptide not a polyhistidine peptide.

Claims 1, 3, 5-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides having at least 75%-100% identity with SEQ ID no. 1. While the amino acid sequence of SEQ ID NO:1 is adequately described in the specification as-filed, thereby providing an adequate basis for the polypeptide of SEQ ID NO:1; there is insufficient written description as to the identity of a polypeptide having at least 75-99% sequence identity to SEQ ID NO:1 that would still maintain the

function of the polypeptide. Consequently, the specification does not provide an adequate written description of a polypeptide having at least 75-99% sequence identity to SEQ ID NO:1.

The specification as filed does not provide adequate written description support for a polypeptide having at least 75-99% sequence identity to SEQ ID NO:1.

Polypeptides having diverse functions are encompassed by the phrase 75-99% identity. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase 75-99% sequence identity and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., Abstract and Sequence-based approaches to function prediction, page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular Abstract and Box 2). Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only SEQ ID No. 1 meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear

that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Claim Rejections - 35 USC § 101

Claim 17 is provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 9-10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Godowski et al US 6255068 as evidenced by Hopp et al Biotechnology vol. 6 p. 204 (1988). Claim 4 is included in this rejection because of the confusion discussed in the above 35 U.S.C. 112, second paragraph rejection.

Godowski et al discloses Gas6 polypeptides ((SEQ ID NO. 2 of patent reads on SEQ ID NO. of the instant invention--see alignments attached as Exhibit A) and variants thereof that have at least 75% sequence identity to Gas6 wherein the variants remain functionally active (col. 5-8). These polypeptides can be epitope tagged with Flag-peptide at the carboxy terminus (col. 17, lines 23+) and cites Hopp et al Biotechnology vol. 6 p. 204 (1988) for the Flag sequence. Hopp et al disclose that the Flag sequence is DKYDDSSDDK (which is SEQ ID No. 2 of the instant invention)(see abstract). The reference also discloses the formulation of compositions containing Gas6 polypeptides (col. 30-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godowski et al US 6255068 in view of applicant's admission on page 7, lines 18-20 of the specification.

Godowski et al discloses Gas6 polypeptides ((SEQ ID NO. 2 of patent reads on SEQ ID NO. of the instant invention--see alignments attached as Exhibit A) and variants thereof that have at least 75% sequence identity to Gas6 wherein the variants remain functionally active (col. 5-8). These polypeptides can be epitope tagged with Flag-peptide at the carboxy terminus (col. 17, lines 23+). The reference also discloses using other epitope tags, but does not disclose the use of poly-histidine. These tag are added to facilitate purification of the Gas6 polypeptide. The reference also discloses the formulation of compositions containing Gas6 polypeptides (col. 30-31).

However, applicant admits that polyhistidine is a "commonly used epitope tag" in addition to Flag.

In view of the suggestion in the reference to use epitope tag for purification and in view of fact that polyhistidine is a commonly used epitope tag, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use either Flag or polyhistidine as the epitope tag to aid in purification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J. Huff
Sheela J Huff
Primary Examiner
Art Unit 1643

sjh

Notice to Comply	Application No. 10/671054 Examiner HUFF	Applicant(s) Young et al Art Unit 1643
NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES		
<p>Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).</p> <p>The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). <input checked="" type="checkbox"/> 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c). <input checked="" type="checkbox"/> 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e). <input type="checkbox"/> 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." <input type="checkbox"/> 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d). <input type="checkbox"/> 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). <input type="checkbox"/> 7. Other Amino acid sequences listed in claims 27-28 should be identified by a sequence identifier <p>Applicant Must Provide:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> An initial or substitute computer readable form (CRF) copy of the "Sequence Listing". <input checked="" type="checkbox"/> An initial or substitute paper copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the specification. <input type="checkbox"/> A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). <p>For questions regarding compliance to these requirements, please contact:</p> <p>For Rules Interpretation, call (571) 272-2510 For CRF Submission Help, call (571) 272-2501/2583. PatentIn Software Program Support Technical Assistance.....703-287-0200 To Purchase PatentIn Software.....703-306-2600</p> <p>PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY</p>		

